§ 452.510e Erythromycin topical gel.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin topical gel is erythromycin in a suitable and harmless gel. Each gram contains 20 milligrams of erythromycin. The erythromycin content is satisfactory if it contains not less than 90 percent and not more than 125 percent of the number of milligrams of erythromycin that it is represented to contain. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1), except with respect to heavy metals.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each request shall contain:

(i) Results of tests and assays on:

(A) The erythromycin used in making the batch for potency, moisture, pH, residue on ignition, identity, and crystallinity.

(B) The batch for erythromycin content.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The erythromycin used in making the batch: 5 packages, each containing approximately 100 milligrams.

(B) The batch: A minimum of 8 containers.

(b) *Tests and methods of assay; erythromycin content.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place approximately 1 gram, accurately weighed, of the product into a high-speed glass blender jar containing 200 milliliters of 0.5 percent (volume by volume) polysorbate 80 in 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), to obtain a stock solution of convenient concentration. Blend for 3 to 5 minutes. Further dilute an aliquot of the stock solution with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).

[53 FR 12415, Apr. 14, 1988; 53 FR 16837, May 11, 1988]

Subpart G [Reserved]

Subpart H—Rectal Dosage Forms

§ 452.710 Erythromycin suppositories.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Erythromycin suppositories contain in each suppository 125 milligrams of erythromycin in a suitable and harmless base. The erythromycin content is satisfactory if it is not less than 90 percent nor more than 120 percent of the number of milligrams of erythromycin that it is represented to contain. The moisture content is not more than 1.0 percent. The erythromycin used conforms to the standards prescribed by § 452.10(a)(1), (i), (iii), (iv), (v), (vii), and (viii), except its moisture content is not more than 5.0 percent.

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The erythromycin used in making the batch for potency, moisture, pH, residue on ignition, identity, and crystallinity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The erythromycin used in making the batch: 10 packages, each containing not less than 500 milligrams.

(*b*) The batch: A minimum of 30 suppositories.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Blend a representative number of suppositories for 3 to 5 minutes in a high-speed glass blender with 200 milliliters of methyl alcohol. Add 300 milliliters of 0.1*M* potassium phosphate buffer, pH 8.0 (solution 3), and blend again for 3 to 5 minutes. Remove an aliquot and dilute with solution 3 to the reference concentration of 1.0 microgram of erythromycin base per milliliter (estimated).